

# Enzymatic Therapy

NATURAL MEDICINES®

January 9, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

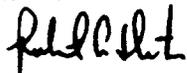
RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	While intake of d-alpha-tocopherol has been the subject of many studies that have shown support for cardiovascular health, new research has indicated that significant benefit is also associated with the activity of other forms of vitamin E: beta, gamma, and delta tocopherol.*	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.



By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/9/04

825 Challenger Drive  
Green Bay, WI 54311 8328  
Ph 920-469 1313  
Fax 888 570-6460  
www.enzy.com

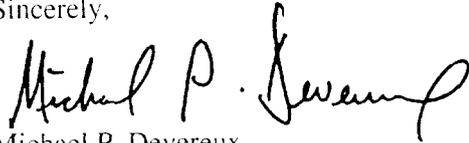
97S 0162

LET 13627

Vitamin E 400 IU 6c

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, prominent initial "M".

Michael P. Devereux  
Chief Financial Officer

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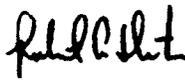
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	Vitamin E is a fat soluble nutrient. It functions in the body in the protection of red blood cell membranes, assists in iron metabolism in the cell, and aids the absorption of vitamin A.* However, vitamin E is primarily recognized for its antioxidant activity.* It is thought to act as a chain breaking antioxidant, which prevents the propagation of lipid peroxidation.*	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/9/04

825 Challenger Drive  
Green Bay, WI 54311 8328

Ph 920 469 1313

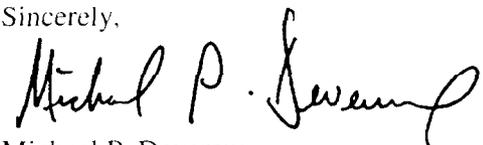
Fax 888 570 6460

www.enzy.com

Vitamin E 400 IU 7c

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

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Michael P. Devereux  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	Observational studies have concluded that intake of vitamin E is associated with support for cardiovascular health.* While the mechanism of action is not completely understood, both human and animal studies have found that vitamin E can delay or prevent low density lipoprotein (LDL) oxidation.*	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/04

825 Challenger Drive  
Green Bay, WI 54311 8328  
Ph 920-469 1313  
Fax 888 570 6460  
www.enzy.com

Vitamin E 400 IU 9c

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

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Michael P. Devereux  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	Cholesterol molecules are formed from a double bond, making them more susceptible to oxidation and free radical formation.* On average, molecules of vitamin E are carried by each LDL particle to protect against oxidation.*	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/04

825 Challenger Drive  
Green Bay, WI 54311 8328  
Ph 920 469 1313  
Fax 888 570 6460  
www.enzy.com

Vitamin E 400 IU 10c

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

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Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

January 11, 2004

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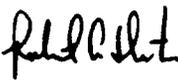
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	Supplemental vitamin E intake has been shown to both boost the antioxidant capacity of LDL particles and support their resistance to oxidation.*	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1,11,04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

Vitamin E 400 IU 11e

# Enzymatic Therapy

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January 11, 2004

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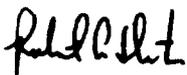
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	Vitamin E 400IU contains a blend of four isomers: alpha, beta, delta, and gamma tocopherol. All are potent antioxidants.* However, each form has unique properties and functions in the body. For example, gamma tocopherol differs from alpha in its ability to detoxify nitrogen dioxide, support healthy cell growth, and inhibit cyclooxygenase-2 (COX-2) activity in macrophages and epithelial cells.*	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

  
By: \_\_\_\_\_

Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 1/11/04

825 Challenger Drive  
Green Bay, WI 54311 8328

Ph 920 469 1313

Fax 888 570-6460

www.enzy.com

Vitamin E 400 IU 12c

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, prominent initial "M".

Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

January 12, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
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5100 Paint Branch Parkway  
College Park, MD 20740

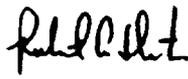
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	Epidemiological studies of dietary vitamin E intake have shown significant support for cardiovascular health.*	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/12/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

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Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

January 12, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	<i>In a four year study of approximately 40,000 men, researchers found that participants who consumed at least 60 IU of dietary vitamin E per day experienced significantly better cardiovascular support than men who consumed less.* A similar study followed over 34,000 postmenopausal women for 7 years, recording their intake of dietary vitamin E. The women with the highest intakes of dietary vitamin E also reported better cardiovascular health support than women consuming less vitamin E.*</i>	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

825 Challenger Drive

Green Bay, WI 54311 8328

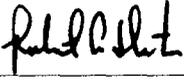
Ph 920 469 1313

Fax 888-570-6460

www.enzy.com

Vitamin E 400 IU 14e

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading

By: 

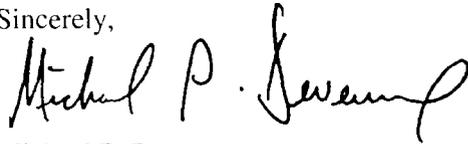
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/2/04

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Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

January 13, 2004

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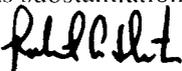
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	A recent study compared the effects of alpha tocopherol alone, and mixed tocopherols in healthy platelet activity in humans. After eight weeks of supplementation, the group receiving mixed tocopherols showed significant support for healthy platelet aggregation, while no similar results were noted in the alpha tocopherol only group.*	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

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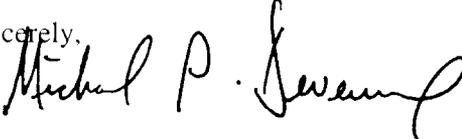
  
By: \_\_\_\_\_

Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 1/13/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

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Michael P. Devereux  
Chief Financial Officer

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	As a potent antioxidant, vitamin E protects cell membranes and fat-soluble areas of the body (such as LDL cholesterol) from free radical damage.*	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/13/04

825 Challenger Drive

Green Bay, WI 54311-8328

Ph 920-469-1313

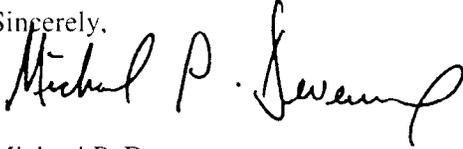
Fax 888-570-6460

www.enzy.com

Vitamin E 400 IU 16c

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

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Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

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January 14, 2004

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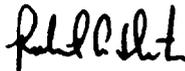
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	New research has documented that the antioxidant activity is greatest from a blend of all the tocopherol forms of vitamin E: alpha, beta, gamma, and delta.*	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading



By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/14/04

825 Challenger Drive  
Green Bay, WI 54311-8328  
Ph 920 469-1313  
Fax 888 570 6460  
www.enzy.com

Vitamin E 400 IU 17c

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitamin E 400 IU	Vitamin E 400 IU provides a blend of natural vitamin E tocopherols for maximum antioxidant activity and free radical detoxification.*	Vitamin E (as d-alpha tocopherol), Mixed Tocopherols (gamma, delta, alpha and beta)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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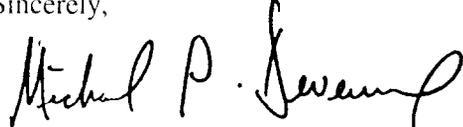
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/14/04

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Michael P. Devereux  
Chief Financial Officer

Vitamin E 400 IU 18c

825 Challenger Drive  
Green Bay, WI 54311 8328

Ph 920 469 1313

Fax 888 572 6460

www.enzy.com